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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,180	01/21/2004	Muthaiyyan Esakki Kannan	1276-37	4776

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Michael E. Carmen, Esq.
M. CARMEN & ASSOCIATES, PLLC
Suite 400
170 Old Country Road
Mineola, NY 11501

EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
4173	

MAIL DATE	DELIVERY MODE
10/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,180	KANNAN ET AL.	
	Examiner	Art Unit	
	Paul W. Dickinson	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/24/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-54* is/are pending in the application.

4a) Of the above claim(s) *8, 10-21, 25-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9,22-24 and 29-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/11/2004 and 2/9/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 9/24/2007 is acknowledged. Applicant's election of the following is also acknowledged: clarithromycin as the pharmaceutically active agent, low molecular weight polyethylene oxide as the primary release modifying agent, high molecular weight polyethylene oxide as the secondary release modifying agent, retrograded starch as the auxiliary release modifying agent, lactose monohydrate as the pharmaceutical additive, hydroxypropyl methylcellulose as the coating.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 3-7, 9, 22-24, and 29-54 are currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-31 and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30-31 recites the limitation "...the low molecular weight polyethylene oxide..." in Claim 1. There is insufficient antecedent basis for this limitation in these claims.

Claim 33-34 recites the limitation "...the high molecular weight polyethylene oxide..." in Claim 1. There is insufficient antecedent basis for this limitation in these claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 29-34, 37, 42-54 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6893660. '660 discloses a solid oral controlled release pharmaceutical composition comprising

(a) a therapeutically effective amount of a pharmaceutically active ingredient, bupropion hydrochloride, 49.83 %wt, and

(b) a controlled release modifying complex comprising

(i) a primary release modifying agent, polyethylene oxide, M.W. 200,000, 19.93 %wt, and

(ii) a secondary release modifying agent, polyethylene oxide, M.W. 5,000,000, 15.95 %wt, and

(iii) an auxilliary release modifying agent, hydroxypropylcellulose, 4.32 %wt.

(see col 1, ln 6-11; Example 1). The composition further comprises the pharmaceutical additives lactose anhydrous, silicon dioxide, and magnesium stearate. The composition is pressed into a tablet.

The examiner is interpreting the phrases "...about 5 percent weight..." and "...about 10 percent weight..." in instant claims 53 and 54 to encompass 4.32 percent weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-7, 9, 22-24, and 29-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6894660 in view of US 5585114 and US 6642276. As stated above, '660 discloses a pharmaceutical composition comprising bupropion hydrochloride, polyethylene oxide (M.W. 200,000), polyethylene oxide (M.W. 5,000,000), hydroxypropylcellulose, lactose anhydrous, silicon dioxide, and magnesium stearate. Although lactose monohydrate as a pharmaceutical additive and hydroxypropyl methylcellulose as a coating are not exemplified, the use of these compounds in these roles is contemplated by the specification (see col 5, ln 26-29, 62). '660 discloses the patent invention has application to drugs that are alkaline and acid-sensitive (col 1, ln 6-11; col 3, ln 2-24; col 3, ln 65 to col 4, ln 10). '660 fails to disclose an example wherein the auxilliary release modifying agent is retrograded starch. '660

further fails to disclose an example wherein the pharmaceutically active ingredient is clarithromycin.

'114 discloses that retrograded amylose (a retrograded starch) is beneficial as a release modifying agent in pharmaceutical composition (see col 1, ln 41-47; col 2, ln 59-67). '114 discloses that retrograded amylose is a preferred release modifying agent because it is resistant to breaking and is subject to little or no disintegration and little or no attack by the enzyme alpha-amylose, nor by acid.

'276 discloses controlled release pharmaceutical formulations of clarithromycin. '276 teaches that macrolides, such as clarithromycin, are alkaline and acid-sensitive (see title; col 1, ln 21-58; see col 2, ln 58-67).

In an effort to find improved clarithromycin pharmaceutical compositions, one skilled in the art would be motivated to combine the disclosures of '660, '114, and '276 to afford the elected invention, with a reasonable expectation of success. One would be motivated to substitute the alkaline, acid-sensitive drug bupropion hydrochloride in the composition disclosed by '660, for the alkaline, acid-sensitive drug clarithromycin. Furthermore, one would be motivated to substitute the hydroxypropyl methylcellulose for acid-resistant retrograded starch.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul W Dickinson
Examiner
Art Unit 4173

October 16, 2007

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER